

# **The Management of the Menopause in the light of EBM**

by

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**Evidence Based Medicine**

**and / or**

***Medicine Based Evidence ?***

MNC

***“Without clinical expertise, practice risks becoming tyrannized by evidence.”***

***“Without current best evidence, practice risks becoming rapidly out of date, to the detriment of patients.”***

**Sackett DL et al., 1996**

**“Evidence alone does not make  
decisions”**

**“The new look of EBM should be research  
enhanced health care”**

*Haynes RB et al. Clinical expertise in the era of evidence based medicine and patient choice (Editorial) ACP Journal Club 2002,Mar-Apr;136(2):A11*

“Clinicians must apply their expertise to assess the patients problem and must also incorporate the research evidence and the patient’s preferences or values before making a management recommendation”

*Haynes RB et al. Evidence-Based Medicine. 1996;1:196-8*

How should we read

*Epidemiology*

and follow

*Evidence Based Medicine ?*

# Information is based on

- . Observational studies  
(*retrospective*)
- . Clinical trials (*prospective*)  
and
- . Experimental studies
  - “in vitro”
  - “in vivo” animals
  - women

# Epidemiological studies

- How were they performed?
- What similarities do they have with our clinical practice?
- How to interpret them?



# Epidemiological Studies

***PLEASE!***

**Do not read only the titles**

**Do not read only the abstracts**

**Do read the full paper**

**Be critical!**

**Make up your own mind!**

# The “language” of the results

- . Absolute risks
- . Relative risks
- . Number needed to treat (NNT)
- . Number needed to harm (NNH)
- . Number needed to screen (NNS)
- . Events per woman / years
- . Events per total number of women

**What is**

**a woman /year ?!**

**100 woman/years = 100 women treated during 12 months**

is it the same as

**100 woman/years = 400 women treated during 3 months**

?

**Do not confuse...**

***Relative Risk***

with

***Absolute Risk!***

**Do not confuse...**

***Morbidity***

with

***Mortality***

**“Not everything that can  
be counted *counts*;**

**and not everything that  
*counts* can be counted”**

*Albert Einstein*

**Women  
are not statistics!**



**They must be treated  
individually.**

. What **do** we know?

Researchers from the University of California, at Davis, claim **clinical trials are reported with misleading statistics**

Mayor S, *BMJ* 2002;321:1353

**“Most randomised trials of new treatments published in leading medical journals (*Ann Intern Med; BMJ; JAMA; Lancet*) are reported in a potentially misleading way”.**

Mayor S, *BMJ* 2002;321:1353

“Most of the trials report results based on relative risk reduction”!

“Only 18 of the papers reviewed considered absolute risk reduction”!

“Only 8 of the 359 trials reported the number needed to treat (N.N.T)”!

Mayor S, *BMJ* 2002;321:1353

# Lessons from the WHI

“...most articles and broadcast segments tended to focus exclusively on either the *small absolute risks* or the *larger relative risks*, neglecting the more even-handed picture that presented both.

Since the **sharply increased *relative risks* got the most play**, news coverage about the trial's findings had an alarming cast.”

Denzer S. Editorial. *Ann Intern Med.*2003;138:352-353

*“The media often failed to understand the complexities and limitations of such trials and came to its own simplified conclusions.”*

***“The nurse’s study and ones like it could be right and the Women’s Health Initiative could be wrong, or vice-versa”***

**Rossouw J, 2003**



***“If each is right it may be because the women in the two types of studies are different in a way that researchers have not yet figured out”.***

**Rossouw J, 2003**

***“May be each study is wrong.  
May be estrogen, in pills, is not  
the chemical to focus on”***

**Rossouw J, 2003**

***“It is quite possible that both are correct. The different results may hinge on the differences between the women who joined the studies”***

**Grodstein F, 2003**

# Effect on the risk of CHD

## WHI Significant increased risk

**RR** 1.29 (CI 1.02-1.63); 29 % increased risk

**AR** 0.37% vs 0.30% (ie, **37** vs **30** events annually per **10.000** women)

## HERS Nonsignificant decreased risk

**RR** 0,99 (CI 0.84-1.17); 1% decreased risk

**AR** 3.66% vs 3.68% (ie, 366 vs 368 events annually per **10.000** women)

“Unlike HERS which showed no benefit or harm after 6.8 years of hormone use, WHI found more heart disease in women taking the combined therapy after 5.2 years.”

“This is a key finding because **WHI** results apply to healthy women while **HERS** involve women with heart disease”

Roussouw J. Release of the Results of the Estrogen Plus Progestin Trial of the Women's Health Initiative: Findings and Implication. Press Conference Remarks July 9, 2002. <http://www.nhlbi.nih.gov/whi/hrtupd/roussouw.htm>

# EBM

can be used **to do...**

and **not** **to do...**

# “Annual Physical Checkup May Be an Empty Ritual”...

“Many tests that are useful, like cholesterol and blood pressure checks, need not be done every year, is said in reports to doctors, policy makers and the public”.

The New York Times; August 2003; U.S. Federal Agency for Healthcare Research and Quality..

# “Annual Physical Checkup May Be an Empty Ritual “ (?!...)”

“No evidence, for example, that routine pelvic, rectal and testicular exams made any difference in overall survival rates for those with no symptoms of illness.” (!?...)

The New York Times; August 2003; U.S. Federal Agency for Healthcare Research and Quality.



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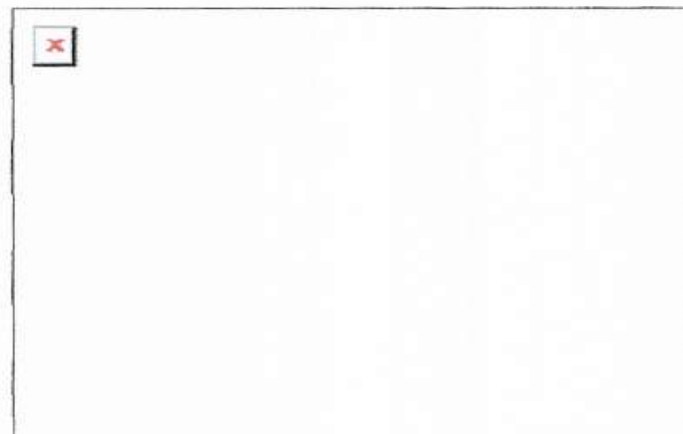
CNN To Go

## Study: Fellatio may significantly decrease the risk of breast cancer in women

Thursday, October 2, 2003 Posted: 9:19 AM EDT (1319 GMT)

**(AP) -- Women who perform the act of fellatio on a regular basis, one to two times a week, may reduce their risk of breast cancer by up to 40 percent, a North Carolina State University study found.**

Doctors had never suspected a link between the act of fellatio and breast cancer, but new research being performed at North Carolina State University is starting to suggest that there could be an important link between the two.



Story Tools

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**Study:    *”Fellatio may significantly decrease the risk of breast cancer in women” !...***

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**“CNN.com./HEALTH”**

***therefore ...***

***When this was read and heard  
all over the World...***

**Most likely, some people  
started thinking that the  
seminal plasma might contain  
an *orally active* protective  
molecule ...**

*h o w e v e r ...*

It was soon found out that **it had been a joke** sent to the Web by one **ironical** N.C. University student ,who wanted to have fun with some epidemiologists! ...

# The Truth?

*“The objective of both basic and clinical science is **to know the truth**”.*

*“Every epidemiologic study, no matter how good or how large, **gives only one view of the truth**”.*

*“It takes many views to come close to seeing the truth”*

Bush TL. *Int J Fertil.*2001;46:56-59